

## REMARKS

### Status of the Claims

Claims 38, 40, 41, 43, 45, 46, 49 and 65-68 are pending and stand subject to an election of species requirement, addressed below.

### Election of Species Requirement

The Examiner asserts that pending claims 38 and 65 are generic to a plurality of patentably distinct species comprising control elements derived from the one of the recited genes. (Election Requirement, paragraph 3).

Applicants provisionally elect, **with traverse**, a first control element derived from heme-oxygenase, a second control element derived from cytochrome P450 1A1, and a third control element derived from PPRE, which read on pending claims 38, 40, 41, 43, 45, 46, 49 and 65-68.

Applicants traverse on the grounds that the asserted election requirement prevents Applicants from claiming their invention. As noted in M.P.E.P. § 803.02:

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984) Broadly, unity of invention exists where [the species] (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

...In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. M.P.E.P. § 803.02, emphasis added.

In the pending case, Applicants' claims necessitate the recitation of multiple control element sequences in a single claim inasmuch as the claims are drawn to animals comprising at least two expression cassettes, where each cassette includes one of the recited control elements and where each cassette includes a different control element. Plainly, Applicants regard their invention as an animal that may be a member of several species and comprising multiple expression cassettes comprising different control elements derived from stress-inducible genes. In sum, given the nature of the pending claims, Applicants submit that the election of species requirement cannot be applied or maintained and, moreover, prevents Applicants from clearly and distinctly claiming their invention in violation of M.P.E.P. § 803.02.

Furthermore, unity of invention, according to M.P.E.P. § 803.02, is clearly present -- all allegedly distinct "species" share a common utility (control elements derived from stress-

inducible genes) and share a substantial structural feature disclosed as being essential to that utility (a nucleotide sequence).

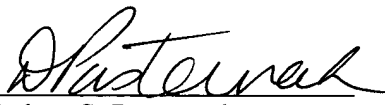
Finally, Applicants also traverse on the grounds that it would not be unduly burdensome to search the allegedly distinct species together. In fact, a search for an animal comprising any two or more different control elements derived from any stress-inducible genes would necessarily reveal relevant art to each of the allegedly distinct species. For example, a search for an animal comprising two stress-inducible control element-containing expression cassettes operably linked to a light generating polypeptide would necessarily reveal art relevant to any of the recited stress-inducible-derived control elements. It would, therefore, not be burdensome (and even save the Office time and resources) to examine the claim as a whole.

It is to be understood that these elections of species are for the purposes of preliminary search and examination only, and that upon allowance of these species, Applicants will be entitled to consideration of additional species in this application.

In view of the foregoing remarks, Applicants respectfully submit that the election of species requirement be withdrawn. Should the Examiner instead choose to make this election of species requirement FINAL, Applicants reserve their right, pursuant to 37 C.F.R. § 1.144, to petition this requirement at any time during the pendency of this application, prior to appeal.

Respectfully submitted,

Date: July 7, 2004

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